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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,979	01/23/2004	John E. Remmers	003-51CIP	5990
20212	7590	07/28/2005	EXAMINER	
THOMPSON LAMBERT SUITE 703D, CRYSTAL PARK TWO 2121 CRYSTAL DRIVE ARLINGTON, VA 22202			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/762,979	REMMERS ET AL.	
Examiner	Art Unit		
Teena Mitchell	3743		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 09 May 2005.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-19,21-31,36-45,47-49,51-58,60-64,77-80,82-89 and 91 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 1-19,21-31,47-49,51-55,77-80,82-89 and 91 is/are allowed.  
 6) Claim(s) 36-45 and 56-58 is/are rejected.  
 7) Claim(s) 60-64 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 5/9/05; 7/18/05.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Objections***

Claims 36 and 64 are objected to because of the following informalities: Claim 36, line 6, "...the gas supplying means..." lacks antecedent basis.

Claim 64, line 1, "...the retrograde flow..." lacks antecedent basis.

Claim 64, line 2, "...the tube..." lacks antecedent basis.

Claim 64, line 2, "...the exit..." lacks antecedent basis. Correction is required.

### ***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:**

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any**

**inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).**

**Claims 36-45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapoport et.al. (5,803,066) in view of Goldstein (6,012,455).**

Rapoport in an apparatus for treating central sleep apnea discloses:

- a blower (86; Col. 3, lines 19-43);
- a mask adapted to fit on a patient's face (20; Col. 3, lines 19-43), the mask operably connected using a tube to gas supplying means (21, 22); and
- a processor (80) adapted to adjust a level of rebreathing to control central sleep apnea in the patient by adjusting an active control element of the apparatus (Fig. 23).

The difference between Rapoport and claim 36 is a dental appliance to reduce mouth leaks.

Goldstein in a nasal mask teaches a dental appliance (24, 42, 92) with a nasal mask (12) providing a means to retain the nose mask, nose piece or nasal tube in proper position without the use of straps, head bands or the like (Col. 2, lines 1-5). With respect to reducing mouth leaks, the mere placing of the dental appliance in the mouth

of a user inherently will reduce mouth leaks, based on the size of the mouth appliance and the person biting down, thereby closing their lips.

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the mask of Rapoport to employ any well known dental appliance doing so would have provided a means to retain the nose mask, nose piece or nasal tube in proper position without the use of straps, head bands or the like including the dental appliance taught by Goldstein.

With respect to claim 37, Rapoport discloses wherein the active control element is variable air resistance means operably connected to an exit (at 25) of the leak resistant patient interface (Fig. 1)

With respect to claim 38, Rapoport discloses wherein the active control element is a unit to adjust a blower output (82).

With respect to claim 39, Rapoport discloses wherein the active control element is a unit to adjust blower output revolutions per minute (82).

With respect to claim 40, Rapoport discloses an exit tube connected to the leak resistant patient interface (at 25).

With respect to claim 41, Rapoport discloses the claimed invention except for the active control element being a recirculator. Applicant has not disclosed that having the active control element being a recirculator solves any stated problem or is for any particular purpose. Moreover, it appears that the active control element would perform equally well with any means. Accordingly, the use of the active control element being a

recirculator is deemed to be a design consideration which fails to patentably distinguish over the prior art of Rapoport.

With respect to claim 42, note rejection of claim 41 above.

With respect to claim 43, Rapoport discloses wherein the active control element is adjusted during a periodic sleep cycle of the patient (Fig. 10, Col. 17, lines 62-67 and Col. 18, lines 1-10 (based on self-adjusting)).

With respect to claim 44, Rapoport discloses wherein the active control element is adjusted over an entire sleeping period (80, 81, 78, 76).

With respect to claim 45, Rapoport discloses wherein the processor (80) receives data from a flow meter (72).

With respect to claim 56, Rapoport discloses a blower (86) and a mask (20) adapted to be fit on the patient's face, the mask operably connected using a tube (21) to the blower, the mask having an exit (Col. 3, lines 19-30), fitting the mask to the patient's face (Col. 6, lines 1-5), adjusting the apparatus such that gas flow from the blower is controlled at a variable rate and essentially constant pressure, the pressure being less than that used to treat obstructive sleep apnea, in order to treat central sleep apnea in the patient (Col. 12, lines 1-60).

**Claims 57-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapoport et.al./Goldstein as applied to claims 38-39 above, and further in view of Haydu (4,757,813).**

The difference between Rapoport/Goldstein and claim 57 the leak resistant patient interface comprising a nasal occlusion device.

Haydu in a patient interface teaches a nasal occlusion device providing a means to assure that breathing will be done through the mouth when the device is in use (Col. 2, lines 10-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the patient interface of Rapoport/Goldstein to employ any well known nasal occlusion device doing so would have provided a means to assure that breathing will be done through the mouth when the device is in use including the nasal occlusion device taught by Haydu.

With respect to claim 58, Rapoport discloses wherein the adjusting step is such that gas pressure from the blower is set below four cm H<sub>2</sub>O pressure (Cols. 3-6; based on needs of the individual the controller sets the pressure .5cm H<sub>2</sub>O increments and adjusts accordingly as needed based on analyzed results).

***Allowable Subject Matter***

Claims 1-19, 21-31, 47-49, 51-55, 77-80, 82-89, and 91 are allowable over the prior art of record.

Claims 60-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The overall combination of an apparatus for treating a breathing disorder where some exhaled gasses from the patient flow retrograde into the tube towards the gas supplying means and away from the exit, a controller operably connected to the variable air resistance means to adjust a level of rebreathing that occurs and maintain a

temporally variable flow of air in the input tube without producing significant deviations in leak resistance patient interface pressure, and the resistance of the exit being set such that during treatment of the breathing disorder in the patient, expiratory air from the patient flows through the tube towards the blower and away from the exit, wherein the apparatus is arranged such that a gas flow from the blower is less than that used to treat obstructive sleep apnea is neither anticipated nor rendered obvious by the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*Teena Mitchell*

Teena Mitchell  
Examiner  
Art Unit 3743  
July 19, 2005